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10/722,657	11/26/2003	Mark B. Dominick	136092SV/YOD GEMS:0244	7668

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EXAMINER	
SQUIRES, ELIZA A	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,657	DOMINICK ET AL.	
	Examiner	Art Unit	
	Eliza Squires	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-16 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6-16 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 December 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed 19 December 2008 has been entered. Claims 3-5 and 17-18 have been cancelled. Claims 1, 6, 15-16, and 19 have been amended. Claims 2 and 7-13 remain as originally presented. Claims 20-24 have been added. Claims 1-2, 6-16, and 19-24 are currently pending in the application.

Response to Amendment

2. The amendment filed 19 December 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added limitation in claims 15, 16, and 19 recites a "machine-readable medium".

The newly added limitation in claim 21 recites "data related to an automatic software upgrade".

The newly added limitation in claim 23 recites that the data reprehensive of the alteration is transmitted "substantially contemporaneous" with the alteration, i.e. the specification says that the system inventories its software and hardware and automatically transmits the data (pp 3 and 4) however no time frame is given to which the system performs the inventory.

This newly added limitation appears to constitute new matter. Applicant did not point out, nor was Examiner able to find, any support for these newly added limitations in the specification as originally filed.

Applicant is requested to clarify the issues discussed above, to specifically point out support for the newly added limitations in the originally filed specification and claims to the extent possible, and to cancel any new matter in the reply to this Office Action.

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 USC 112, first paragraph for at least the same rationale as discussed above, and incorporated herein.

The newly added limitation in claims 15, 16, and 19 recites a "machine-readable medium".

The newly added limitation in claim 21 recites "data related to an automatic software upgrade".

The newly added limitation in claim 23 recites that the data reprehensive of the alteration is transmitted "substantially contemporaneous" with the alteration, i.e. the specification says that the system inventories its software and hardware and automatically transmits the data (pp 3 and 4) however no time frame is given to which the system performs the inventory.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claims 15, 16, 19, 21, and 23** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As per claim(s) **15, 16, 19, 21, and 23**, these claims are rejected for at least the same rationale as discussed above, and incorporated herein.

The newly added limitation in claims 15, 16, and 19 recites a "machine-readable medium".

The newly added limitation in claim 21 recites "data related to an automatic software upgrade".

The newly added limitation in claim 23 recites that the data reprehensive of the alteration is transmitted "substantially contemporaneous" with the alteration, i.e. the specification says that the system inventories its software and hardware and automatically transmits the data (pp 3 and 4) however no time frame is given to which the system performs the inventory.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 22 and 24** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The term "substantially contemporaneous" in **claim 22** is a relative term which renders the claim indefinite. The term "substantially contemporaneous" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

b. **Claim 24** recites "wherein the signal representative of the change is automatically transmitted to the remote computer where the change occurs". This is unclear as it seems to suggest that the change occurs in the remote computer while in claim 12 the change occurs in the medical device. This may present a new matter, however it is difficult to determine due to this clarity issue. Examiner speculates that "where the change occurs" was not intended, so for the purpose of examination the claim will read "...wherein the signal representative of the change is automatically transmitted to the remote computer."

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. **Claims 1, 6, 11-16, and 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya*.

10. **As to claim 1,** *Yokoi* discloses a method for producing a service report for a service performed on a medical device by a service provider, comprising:

operating a computer system to receive medical device data transmitted automatically to the computer system from a medical device via a communications network (abstract and column 3 lines 18-27 and column 4 lines 19-47);

operating the computer system to receive service provider data transmitted automatically to the computer system via the communications network, wherein the service provider data comprises information related to the service performed on the medical device (abstract and column 3 lines 18-27, column 3 lines 45-61, and column 4 lines 19-47); and

operating the computer system to generate a service report based on the medical device data and the service provider data (abstract and column 3 lines 18-27 and column 4 lines 19-47).

However, *Yokoi* does not explicitly teach that the medical device is operable to detect an alteration of hardware or software and this information is transmitted automatically. *Kaseya* discloses:

wherein a computer is operable to detect an alteration of software, and wherein the data transmitted automatically by the medical device is representative of the alteration (pages 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the reporting system of *Yokoi* with the inclusion of the automatic detection system of *Kaseya* in order to ensure the existence of the correct operational parameters within a medical device (*Yokoi* column 8 lines 26-38).

11. **As to claim 6,** *Yokoi* discloses a method for facilitating the preparation of a service report for a medical device; comprising:

providing medical device service data automatically from the medical device to a computer system via a communications network (abstract and column 3 lines 18-27 and column 4 lines 19-47);

providing service provider data automatically to the computer system via a communications network, wherein the service provider data comprises information related to the service performed on the medical device (abstract and column 3 lines 18-27, column 3 lines 45-61, and column 4 lines 19-47); and

generating a service report based on the service data and the service provider data automatically using the computer system (abstract and column 3 lines 18-27 and column 4 lines 19-47).

However, *Yokoi* does not explicitly teach that the medical device is operable to detect an alteration of hardware or software and this information is transmitted automatically. *Kaseya* discloses:

wherein the medical device is operable to detect an alteration of at least one of medical device hardware or medical device software and wherein the medical device data transmitted automatically by the medical device is representative of the alteration (pages 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the reporting system of *Yokoi* with the inclusion of the automatic detection system of *Kaseya* in order to ensure the existence of the correct operational parameters within a medical device (*Yokoi* column 8 lines 26-38).

12. **As to claim 11,** see the discussion of claim 6, additionally, *Yokoi* discloses the method comprising transmitting the service report from the computer system to a remote device to enable a user to revise the service report (column 6, lines 6-19).

13. **With respect to claim 12,** *Yokoi* discloses a medical information system, comprising:

a medical device comprising hardware and software, the medical device being operable to communicate with a remote computer via a communication system (column 3, lines 46-58).

However *Yokoi* does not disclose that the device is operable to detect a change in hardware and software. *Kaseya* discloses that the system is operable to detect a change in each of the hardware and the software and to automatically transmit a signal representative of the change to the remote computer (page 1).

14. **With respect to claim 13,** see the discussion of claim 12, additionally, *Yokoi* discloses the medical information system wherein the medical device is a medical imaging system (column 1, lines 12-22).

15. **As to claim 14,** see the discussion of claim 12, additionally, *Yokoi* discloses the medical information system as recited in claims 12, wherein the communication system comprises a network (column 4, lines 42-47).

16. **As to claim 15,** *Yokoi* discloses a machine-readable medium comprising:

machine-executable programming instructions physically stored in the machine-readable

medium, wherein the programming instructions enable a processor- based device to produce a service report for a medical device based on medical device data received automatically from the medical device and service provider data received automatically from a remote device (abstract, column 3 lines 18-27 and column 4 lines 19-47, and figure 2).

However, *Yokoi* does not explicitly teach that the medical device is operable to detect an alteration of hardware or software and this information is transmitted automatically. *Kaseya* discloses:

wherein the medical device is operable to detect an alteration of at least one of medical device hardware or medical device software, and wherein the medical device data transmitted automatically by the medical device is representative of the alteration (pages 1 and 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the reporting system of *Yokoi* with the inclusion of the automatic detection system of *Kaseya* in order to ensure the existence of the correct operational parameters within a medical device (*Yokoi* column 8 lines 26-38).

17. **As to claim 16,** see the discussion of claim 15, additionally, *Yokoi* discloses the machine-readable medium wherein the programming instructions enable the processor-based device to produce a service report containing data representative of at least one of a hardware and a software change to the medical device (column 3 lines 18-27 and column 4 lines 19-47, and figure 2).

18. **As to claim 19,** see the discussion of claim 15, additionally, *Yokoi* discloses the machine readable medium wherein the system enables a user to use the remote device to revise the service

report and to transmit the revised service report to the computer system via the network (column 6, lines 6-19).

19. **As to claim 20,** see the discussion of claim 1, additionally, *Yokoi* discloses the method comprising operating the computer system to communicate the service report to a parts database via the communication network (*Yokoi* column 7 lines 39-67).

20. **As to claim 21,** see the discussion of claim 1, additionally, *Yokoi* discloses the method wherein the service provider data comprises data related to an automatic software upgrade (*Yokoi* column 14 lines 49-67).

21. **As to claim 22,** see the discussion of claim 1, additionally, *Kaseya* discloses the method wherein the medical device data comprises an inventory of software and hardware in the medical device (*Kaseya* page 1).

22. **As to claim 23,** see the discussion of claim 1, additionally, *Kaseya* discloses the method wherein the medical device data representative of the alteration is transmitted automatically from the medical device to the computer system substantially contemporaneous with occurrence of the alteration (*Kaseya* page 1 and 2).

23. **As to claim 24,** see the discussion of claim 1 and 12, additionally, *Kaseya* discloses the system wherein the signal representative of the change is automatically transmitted to the remote computer (*Kaseya* pages 1 and 2).

24. **Claims 2 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* in further view of *Krasner*.

25. **As to claim 2,** see the discussion of claim 1, however, *Yokoi* and *Kaseya* do not explicitly disclose the tracking of a service provider. *Krasner* discloses the method wherein the service provider data comprises GPS location data from a remote device transported by the service provider (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *Krasner* in order to more accurately locate and verify the location of personnel to better confirm that the service was truly rendered.

26. **As to claim 9,** see the discussion of claim 6, additionally, *Yokoi* discloses a service report (column 3, lines 14-26 and column 4 lines 42-47). However, *Yokoi* does not explicitly disclose the tracking of a service provider. *Krasner* discloses the method wherein the service provider data comprises GPS location data for the service provider (column 22, lines 41-67 and column 23, lines 1-8).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* with *Krasner* in order to more accurately locate, verify and document the location of personnel to better confirm that the service was truly rendered.

27. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* in further view of the manual published by the *FDA* last revised 1/1/97 entitled "Quality System Manual".

28. **As to claim 7,** see the discussion of claim 6, however, *Yokoi* and *Kaseya* do not disclose that the service report comprises a list of services performed. *FDA* discloses the method wherein the service report comprises a listing of services performed by the service provider based on the service provider data (service reports section, page 7).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *FDA* in order to comply with governing body regulations for contents of a service report.

29. **Claims 8 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yokoi* in view of *Kaseya* in further view of "Reliable Design of Medical Devices" by *Richard C. Fries*.

30. **As to claim 8,** see the discussion of claim 6, however, *Yokoi* and *Kaseya* do not explicitly disclose that a listing of parts is included in the service report. *Fries* discloses the method wherein the service report comprises a listing of parts replaced by the service provider based on the service data (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

31. **As to claim 10,** see the discussion of claim 6, however, *Yokoi* and *Kaseya* do not explicitly disclose time keeping data as a service record component. *Fries* discloses the method wherein the service report comprises service time data for the service provider (section 28.1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify *Yokoi* and *Kaseya* with *Fries* to provide data for a meaningful analysis of product reliability as disclosed by *Fries* (section 28.1).

Response to Arguments

32. Applicant's arguments filed 19 December 2008 have been fully considered but they are not persuasive.

33. The objection to the drawings are withdrawn in light of Applicants amendment to the drawings and to the specification.

34. The rejections under 35 USC 112 as presented in the prior office action are withdrawn in light of applicants amendment to claim 1, however new grounds of rejection have been included in this office action necessitated by Applicants amendment.

35. The rejections under 35 USC 101 have been withdrawn in light of Applicant's amendment to claims 15-17.

36. The rejections under 35 USC 102 have been withdrawn in light of Applicant's amendment.

37. With regard to the rejections under 35 USC 103, Applicant argues on pages 12 and 13 of the remarks that the combination of the medical device of *Yokoi* and the auditing system of *Kaseya* fail to disclose all the limitations of "a medical device that is operable to detect an alteration of at least one of medical device hardware or medical device software, and where the medical device data transmitted automatically by the medical device is representative of the alteration to the medical device".

38. *Yokoi* teaches a medical device that automatically and manually records data related to the hardware and software of the system however this system does not automatically transmit data representative of a change to hardware or software (*Yokoi* column 3). *Kaseya* teaches performing "hardware and software audits" (*Kaseya* page 1) as well as being able to get instant

notification (*Kaseya* page 2) when "a user installs a new application" (i.e. performs a software change) and "a user removes or adds a PCI card" (i.e. performs hardware changes). While *Kaseya* does not teach a medical device, the MRI apparatus which contains hardware and software (medical device) of *Yokoi* when modified by *Kaseya* yields a medical device with the functionality of *Kaseya* and required to meet the limitations of the claim.

39. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., an audit performed in a "self aware" manner) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). As recited in the claim, *Yokoi* modified with *Kaseya* perform the claimed function "a medical device that is operable to detect an alteration of at least one of medical device hardware or medical device software, and where the medical device data transmitted automatically by the medical device is representative of the alteration to the medical device".

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eliza Squires whose telephone number is (571)270-7052. The examiner can normally be reached on Monday through Friday 8 am - 4 pm Eastern Standard Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. S./
Examiner, Art Unit 3626
2/19/09

/C. Luke Gilligan/
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